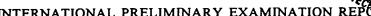
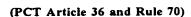
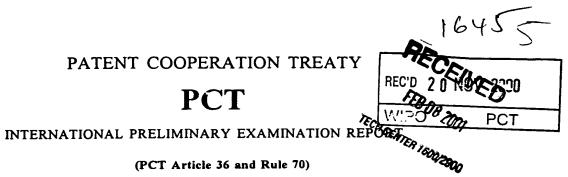
PATENT COOPERATION TREATY

PCT







Applicant's or agent's file reference 311.067/PCT/		TION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)		
International application No.	International filing date (day/mon	th/year) Priority date (day/month/year)		
PCT/US99/06799	30 MARCH 1999	30 MARCH 1998		
International Patent Classification (IPC) Please See Supplemental Sheet.	or national classification and IPC			
Applicant BAYLOR COLLEGE OF MEDICINE				
Examining Authority and is	transmitted to the applicant acc	een prepared by this International Preliminary cording to Article 36.		
2. This REPORT consists of a				
been amended and are th	panied by ANNEXES, i.e., sheets to basis for this report and/or sheet tion 607 of the Administrative Ins	of the description, claims and/or drawings which have s containing rectifications made before this Authority. structions under the PCT).		
These annexes consist of a to	otal of <u>//</u> sheets.	_		
3. This report contains indication	is relating to the following item	18:		
I X Basis of the repo		•		
II Priority				
III Non-establishmer	nt of report with regard to nove	lty, inventive step or industrial applicability		
IV X Lack of unity of	invention			
V X Reasoned statemer citations and expla	nt under Article 35(2) with regard mations supporting such statemen	to novelty, inventive step or industrial applicability;		
VI Certain documents	cited			
VII Certain defects in t	he international application			
VIII X Certain observation	s on the international application			
Date of submission of the demand	Date of	completion of this report		
01 NOVEMBER 1999	11 (OCTOBER 2000		
Name and mailing address of the IPEA		zed officer Super Dayles		
Commissioner of Patents and Traden Box PCT		BERT A. ZEMAN		
Washington, D.C. 20231	Telepho			
Facsimile No. (703) 305-3230	relepho	7110 110. (703) 308-0190		

International application	No.
PCT/US99/06799	

I. E	Basis of th	ne report		
1. Wi	th regard to	the elements of the interna	utional application:*	
x	-	rnational application as		
	┙., ,	cription:	<i>3.</i> 7	
x	pages _			as originally filed
	pages _			filed with the demand
	pages _	 	, filed with the letter of	
	pages _		, med with the letter of	
x	the clair	ms:		
جنا	pages _	62-65		, as originally filed
	pages _	NONE	, as amended (together with any	
	pages _			, filed with the demand
	pages _	NONE	, filed with the letter of	
_				
X	the drav			1.1
		NONE		, as originally filed
	pages _		, filed with the letter of	, filed with the demand
	pages _	NONE	, filed with the letter of	
Γv	the sean	ence listing part of the d	escription:	
X				as originally filed
	pages -	NONE		, filed with the demand
	pages	NONE	, filed with the letter of	
	the lang	uage of publication of t	rnished for the purposes of international search of the international application (under Rule 48.3(b)) hished for the purposes of international preliminary ex).
	reliminary	examination was carried	r amino acid sequence disclosed in the international out on the basis of the sequence listing:	al application, the international
L_	containe	ed in the international a	pplication in printed form.	
	filed tog	gether with the internati	onal application in computer readable form.	
] furnishe	d subsequently to this A	Authority in written form.	
_	-		Authority in computer readable form.	
느	j	• •		havend the displacement in the
	internation	ement that the subsequent onal application as filed	atly furnished written sequence listing does not go has been furnished.	beyond the disclosure in the
	The state been fun		recorded in computer readable form is identical to the	ne writen sequence listing has
4. X	The am	endments have resulted	in the cancellation of:	
7.	তি	e description, pages	NONE	
			NONE	
		e claims, Nos.	NONE	
		e drawings, sheets/fig		
5. <u>X</u>			some of) the amendments had not been made, since the	ey have been considered to go
in	nlacement s	heets which have been furn	indicated in the Supplemental Box (Rule 70.2(c)).** sished to the receiving Office in response to an invitation are not annexed to this report since they do not con	under Article 14 are referred to ntain amendments (Rules 70.16
		nent sheet containing such	a amendments must be referred to under item 1 and	annexed to this report.

International application No.
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IV. Lack of unity of invention	
1. In response to the invitation to restrict or pay additional fees the applicant has:	
restricted the claims.	
paid additional fees.	
paid additional fees under protest.	
neither restricted nor paid additional fees.	
2. X This Authority found that the requirement of unity of invention is not complied with and chose, according not to invite the applicant to restrict or pay additional fees.	ing to Rule 68.1,
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is	
complied with.	
x not complied with for the following reasons:	
Please See Supplemental Sheet.	
4. Consequently, the following parts of the international application were the subject of international preliminary ex in establishing this report:	amination
X all parts	
the parts relating to claims Nos	

International application No.

		PC1/0399/06/99	
V. Reasoned statement under Article 35 citations and explanations supporting		rd to novelty, inventive step or industrial ent	applicabilit;;
. statement			
Novelty (N)	Claims	10-11, 13-16, 21-24, 27	YES
, ,	Claims	1-9, 12, 17-20, 25-26	NO
Inventive Step (IS)	Claims	27	YES
midual sup (is)	Claims	1-26	NO

Industrial Applicability (IA)	Claims	1-27	
	Claims	NONE	NO
citations and explanations (Rule Claims 1-9, 12, 17-20 and 25-26 lacks novelt		rticle 33(2) as being anticipated by GEN HOSPIT	AL CORP. (WO
97/20463).	,		
97/20463). GEN HOSPITAL CORP disclos various maladies by inducing apoptosis in the specifically address the use of inducible leth.	e inducible vec e target cells/ti al molecules to	3) as being obvious over GEN HOSPITAL COR tors for the delivery of a lethal molecule for the saues (see example 2). While GEN HOSPITAL treat prostate hypertrophy or prostate cancer (as of GEN HOSPITAL CORP, to treat any maladates.	treatment of CORP. do not and indirectly
Claim 27 the criteria set out in PCT Article using inducibly lethal molecules to determine	33(2)-(3), beca e the biological	use the prior art does not teach or fairly suggest role of various cell types.	t a method of
Claims 1-27 meet the criteria set out in PCT	Article 33(4)	for industrial applicability.	
NEW CITATIONS			

International application No.

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VIII.	Certain observations on the international application
	llowing observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully ted by the description, are made:

The description is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 5 because it fails to adequately enable practice of the claimed invention because: the methods recited in claims 12-25 are drawn to treating diseases. This requires in vivo application of the vectors recited in claims 1-5. The disclosure is totally silent on what such treatment protocols would entail.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below: IPC(7): A01N 37/18, 43/04; C07K 01/00; C12N 5/10, 15/00 and US C1.: 514/2, 44; 530/350; 536/24.1,435/410

I. BASIS OF REPORT:

5. (Some) amendments are considered to go beyond the disclosure as filed:
ENTRY OF SUBSTITUTE DISCLOSURE DATED 08 NOVEMBER 1999 (PCT/ISA/217) WAS REFUSED

IV. LACK OF UNITY OF INVENTION:

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2, and 13.3 is not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-6, drawn to conditionally lethal molecules and nucleic acids encoding said molecules.

Group II, claim(s) 7-9, drawn to gene therapy vectors.

Group III, claim(s) 10, drawn to a transgenic animal.

Group IV, claim(s) 11, drawn to a method of making a transgenic animal.

Group V, claim(s) 12-16, drawn to methods of treating a disease (atherosclerosis).

Group VI, claim(s) 17-20, drawn to methods of inducing tumour regression.

Group VII, claim(s) 21-22, drawn to methods of reducing PSA levels.

Group VIII, claim(s) 23-24, drawn to methods of affecting rate of cell proliferation.

Group IX, claim(s) 25-26, drawn to methods of inducing apoptosis.

Group X, claim(s) 27, drawn to method of determining biological role of a cell type.

The inventions listed as Groups I-X do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first-recited product, conditionally lethal molecules. Further pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT rule 13.2 and that each of such products and methods accordingly defines a separate invention.